DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

m2120

June 15, 1999

cc: ~~HFI-35~~
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99-33

Mr. Gary Date
President
Advertising Unlimited, Inc.
1000 Highway 4 South
Sleepy Eye, Minnesota 56085

Dear Mr. Date:

During our inspection of your Advertising Unlimited, Inc. over-the-counter (OTC) drug repacking operation and Class I medical device manufacturing operation, located in Red Wing, Minnesota, our investigator found serious violations of the Current Good Manufacturing Practices (GMPs) for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 211 (21 CFR 211). Your repacked OTC drug products are adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

The violations observed during our inspection include but are not limited to the following:

1. Failure to perform, for each batch of drug product, appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release [21 CFR 211.165(a)]. In that no finished product testing for identity and strength are performed on packaged OTC drug products.

2. Failure to establish the reliability of your supplier's analysis through appropriate validation of your supplier's test results at appropriate intervals [21 CFR 211.84(d)(2)]. In that the Certificate of Analysis (COA) received from your bulk supplier for finished product received in bulk totes has not been validated on a periodic basis.

3. Failure to determine expiration dates by appropriate stability testing [21 CFR 21.137(a)]. In that no stability data could be provided (sunscreen products) and/or stability data is insufficient (antiseptic lotion, first aid cream, and antiseptic towelettes) to support the 3 year expiration date on OTC drug products.

4. Failure to follow your written stability testing program [21 CFR 211.166]. In that the stability sampling/testing has not been conducted on a routine basis as per your standard operating procedure. For example, only microbial assays have been conducted on the antiseptic lotion, no strength or identity.

   In addition, our investigator determined that your firm manufactures adhesive bandages. Adhesive bandages are devices as defined by Section 201(h) of the Act. These devices are adulterated within the meaning of Section 501 (h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with Quality System Regulation (QSR), as specified in 21 CFR 820, as follows:

   Failure to validate the process with a high degree of assurance and approve the process according to established procedures [21 CFR 820.75]. In that, your ~~~~ ~~~~ sterilization process of adhesive bandages has not been validated to date, although adhesive bandages have been, and continue to be, distributed.

The above indication of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and or injunction. This is official notification that FDA expects all your locations to be in compliance.

In addition, 21 CFR 211.84(d)(2) also requires you to perform at least one specific identity test on the incoming bulk OTC drug.

You should notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Compliance Officer Carrie A. Hoffman at the address on the letterhead.

Sincerely,

James A. Rahto
Director
Minneapolis District

CAH/rfk

xc: Gary E. Nordmark
Advertising Unlimited, Inc.
5151 Moundview Drive
Red Wing, MN 55066